

REMARKS

By entry of this amendment, claims 29-51 are pending. No new matter will be incorporated into the present application by entry of this Amendment.

The Examiner has rejected claims 1 and 46 and objected to claims 2 – 45 and 47-51, as indicated in the Office Action Summary. However, claims 1-28 were cancelled by the previous amendment, therefore we are uncertain how to interpret the Examiner's rejection and objection. Furthermore, the response discusses only independent claims 1 and 46, and does not discuss the other independent claim, claim 29. However, claims 29 and 46 are the only pending independent claims. We therefore believe the Examiner's discussion of claim 1 was intended to refer to claim 29 and we base our response on this belief. Also, since the text of the office action does not include an explanation of the objection, we are not clear on the grounds for objection and assume that this was an honest error in the Office Action Summary.

The Examiner rejected claims 1 and 46 under 35 USC 112 first paragraph as failing to comply with the enablement requirement. The Examiner notes that the claims do not include properties noted in the background section of the specification.

Applicant respectfully traverses this rejection. The application fully discloses each of the limitations of the independent claims. A self assembling monolayer is a composition, typically a surfactant composition, sufficient to form a substantial monolayer upon a particular surface under conditions of use. Examples of SAM-forming molecules are disclosed throughout the application. Latent reactive groups include reactive groups which may be activated by radiation energy, such as photoreactive groups. Examples of latent reactive groups are provided throughout the application,

including, for example, the photoreactive groups described in detail in pages 19 – 21 of the application.

To fulfill the enablement requirement of 35 USC 112 first paragraph, a claim must be supported by sufficient information in the disclosure to enable one skilled in the pertinent art to make and use the claimed invention. In determining whether a claim is enabled by a disclosure, the following factors from *In re Wands*, 858 F.2d 731 (see also MPEP 2164.01(a)) provide a useful framework for analysis.

(A) The breadth of the claims – The claims are limited to self assembling monolayer molecules covalently adjoined to one or more surfaces with latent reactive groups. As previously mentioned, the disclosure defines and provides examples of the self assembling monolayer molecules and latent reactive groups claimed in the present application. Furthermore, the claim further provides the limitation that the latent reactive groups covalently adjoin the SAMs molecules to the surface of the medical device, thereby further clarifying the types of components that may be utilized in the present invention and offering claims that are relatively narrow in scope.

(B) The nature of the invention – The invention relates to polymer chemistry, and more specifically the use of polymers to coat a medical device. Thus the nature of the invention is relatively sophisticated and would be understood by one of ordinary skill in the art.

(C) The state of the prior art – Self assembling monolayers are known in the prior art. The use of latent reactive groups, such as those utilized in photochemistry, is also known for attaching molecules to surfaces. However, the combination of self assembling monolayers and latent reactive groups for coating a medical device was not

previously known in the art. Examples of self assembling monolayers and of latent reactive groups useful in the invention are provided in the specification. Thus the combination and use of such components as claimed in the present application has not been previously disclosed or suggested in the prior art and provides a novel and nonobvious coated medical device.

(D) The level of one of ordinary skill – The level of ordinary skill of one in the art is high, such as a Ph.D. in polymer chemistry with experience in coating technology. Thus one of ordinary skill in the art would understand the technology taught by the application and would be able to make and use the invention.

(E) The level of predictability in the art – Those of ordinary skill in the art would be familiar with self assembling monolayers after review of the disclosure and with their relevant background. Furthermore, they would also know how to use latent reactive groups in combination with the SAMs molecules in view of the information provided in the disclosure. Therefore, provided with the guidance supplied by the application, one of ordinary skill in the art would know how to coat a medical device with a self assembling monomer using latent reactive groups.

(F) The amount of direction provided by the inventor – Examples of self-assembling monolayers compositions and latent reactive groups useful in embodiments of the invention are provided in the specification, as well as examples of various ways to use them as a coating. Thus the specification provides ample direction on how to make and use the invention.

(G) The existence of working examples – Several working examples are described in detail in the application. These examples provide specific teachings regarding how to make and use the invention.

(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure – A person of ordinary skill in the art would understand how to make and use the invention, based on the disclosure and the working examples provided. Little experimentation would be needed.

Based on this analysis, Applicant asserts that the claims are fully enabled by the specification such that one of ordinary skill in the art would be able to make and use the claimed invention without undue experimentation. The Examiner noted that limitations calling for certain properties were not included in the claims.

Applicant maintains that claiming of these properties are not required in order to enable the invention. Furthermore, inclusion of these properties in the claims would add nothing to the enablement of the invention as taught by the specification.

The Examiner also rejected claims 1 and 46 under 35 USC 102(e) or (b). The prior art cited by the Examiner includes: U.S. Patent No. 6,468,649 to Zhong; LaVan et al., Small-scale systems for in vivo drug delivery, Department of Mechanical Engineering, Yale University; Noble et al., Biomaterials Tutorial, *Drug Delivery Systems*; McAllister et al., Microfabricated microneedles for gene and drug delivery, *Annu. Rev. Biomed. Eng.* 2, 289-313 (2000); and Santini et al., A controlled-release microchip, *Nature* 397, 335-338 (1999). Applicant respectfully traverses this rejection on the grounds that none of the disclosures teach a coated medical device including a self assembling monolayer adjoined to one or more surfaces with latent reactive groups.

Furthermore, none of the disclosures teach covalently adjoining a self assembling monolayer to a surface using latent reactive groups.

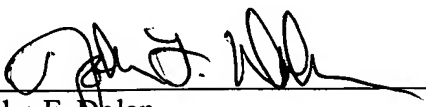
Zhong discloses a hydrophilic coating for a medical device. The coating includes a polyfunctional crosslinking agent having functional groups which react with organic acid groups. Zhong does not disclose latent reactive groups and does not disclose covalently adjoining a self assembling monolayer to a surface. Because Zhong fails to teach all of the elements of the claims, Zhong does not anticipate claims 29 or 46.

The excerpt from the LaVan et al. reference quoted by the Examiner includes a general discussion regarding drug delivery from microsystems. Noble et al. discloses polymeric micelles for hydrophobic drug delivery. McAllister discloses in general terms the concept of delivering drugs using microneedles. None of these references teach the use of a self-assembling monolayer coating. Furthermore, none of the references teach the use of latent reactive groups with a self assembling monolayer, and none teach the use of latent reactive groups to covalently adjoin a self assembling monolayer to a surface. Thus none of the cited references, alone or in combination, anticipate claims 29 or 46.

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,



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